NEW JERSEY COMMISSION ON BRAIN INJURY RESEARCH

RESEARCH PROGRAM GUIDELINES

INTRODUCTION

Approximately 175,000 New Jersey residents suffer from traumatic injuries that damage the brain. Approximately 12,000 new brain injuries occur each year in New Jersey. The economic consequences of the resulting physical disabilities are enormous. Medical and long term care costs to the nation's economy are estimated to be 48 billion dollars annually. The personal toll on individuals and families with brain injuries and their communities is incalculable.

Therefore, in January 2004, Governor James E. McGreevey signed legislation creating the New Jersey Commission on Brain Injury Research (NJCBIR), allocating funding to the New Jersey Brain Injury Research Fund.

The charge to the NJCBIR is:

> The NJCBIR will solicit and approve support of research projects, administer the awards through research grants, and promote development of brain injury research projects within the State of New Jersey that focus on treatments and cures. Because the majority of brain injuries within the State are a result of traumatic events, the Commission is particularly interested in funding projects that focus on the treatment and cures of traumatic brain injuries. The NJCBIR will compile a research directory of all traumatic brain injury research projects being conducted within the State, and provide the Governor and the Legislature with an annual report by January 30th of each year describing the status of the NJCBIR's activities and the results of its funded research projects.

PROGRAM OBJECTIVES

The NJCBIR is committed to accelerating research to develop effective interventions and cures for the disabilities associated with traumatic brain injury. Its primary objectives are:

- To advance the field of brain cell repair and regeneration in the New Jersey research community by encouraging established scientists to apply their expertise to the brain.
- To foster collaborative, interdisciplinary approaches to brain injury research.
- To develop models of neural repair and regeneration that establish a basis for additional scientific investigation.
- To develop models of neural repair and regeneration after brain injury that can lead to clinical interventions.
- To promote dissemination of the research findings generated by those scientists supported by the NJCBIR.

NJCBIR awards are intended to promote collaboration among brain injury researchers in New Jersey and encourage innovative research, not to provide long-term support. Grantees are eligible to apply for funding for additional research projects; all applications will be reviewed competitively.

FUNDING PRIORITIES

The New Jersey Commission on Brain Injury Research will fund research activities that hold promise of developing effective interventions and cures for the disabilities associated with traumatic brain injury. The areas of research listed below highlight the focus of current NJCBIR emphasis and funding:

- Studying strategies to promote neuronal growth and survival, encourage the formation of synapses, enhance appropriate myelination, restore axonal conduction, replace or regenerate injured brain cells, or otherwise improve function after brain injury.

- Evaluating efficacy of drugs and other interventions that prevent or reduce secondary neuronal injury or providing insight into the mechanisms causing progressive damage.

- Defining anatomical characteristics of brain injury in well-defined animal models and in the human brain, specifically documenting the cellular systems vulnerable to injury and the functional losses which occur as a result thereof.

- Translational research on the mechanism and interventions that promote recovery of function after brain injury.

- Demonstrating the efficacy of innovative rehabilitation strategies based on basic research that offer promise to promote recovery of function through their clinical application.

ELIGIBILITY

Qualifying Institutions: For the purpose of all NJCBIR grants, a qualifying institution is defined as any academic institution, research organization, public or private institution or other entity, located in the State of New Jersey, with a demonstrated capability to conduct grant funded research, and specifically approved by the vote of the Commission, but in no event can an individual be a qualifying institution. All applicants, organizations/institutions must be located within the State of New Jersey.

PROTECTION OF HUMAN SUBJECT, ANIMAL WELFARE, AND RECOMBINANT DNA

Compliance with National Institutes of Health regulations for the protection of human subjects, animal welfare and recombinant DNA is required for all grants. Inclusion of women and minorities in clinical trials is a target objective for all grants.

a. NJCBIR supports compliance with NIH regulations, OHRP and institutional guidelines defined for the protection of human subjects in research. Violations of these regulations and guidelines must be reported and reviewed by the appropriate institutions and NJCBIR, including but not limited to OHRP, the IRB overseeing the research, the associated institution and the laboratory's senior scientist.

b. NJCBIR shall have the right to arrange for observation and/or auditing w/o prior notice of any research activity and research records associated with research funded by NJCBIR.

It is the responsibility of the applicant as a potential recipient of a NJCBIR grant to assure that the rights and welfare of all human subjects used in any NJCBIR sponsored research are protected. Any applications involving human subjects must be reviewed and approved by the appropriate institutional review board.

It is the responsibility of the applicant as a potential recipient of a NJCBIR grant to assure proper care and treatment of all laboratory animals used in any NJCBIR sponsored research. Any applications involving laboratory animals must be reviewed and approved by the appropriate institutional review board.

It is the responsibility of the applicant as a potential recipient of a NJCBIR grant to assure that the physical and biological containment needed for research involving any recombinant DNA molecules is within policies set out in the current "National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules." Any applications involving recombinant DNA molecules must be reviewed and approved by the appropriate institutional review board.

RESEARCH GRANTS AVAILABLE

Individual Research Grant

The NJCBIR will fund Individual Research Grants with an emphasis on (1) strategies to promote neuronal repair and regeneration after traumatic brain injury, or (2) translational research that establishes the relevance of basic research findings to clinical application in human subjects. Applicants are encouraged to apply for a one-year or two-year award. Maximum funding is up to $150,000 per year including direct and indirect costs (10% maximum for the latter).

The goals of this program are (1) to encourage investigators to undertake research on neural protection, repair and regeneration after traumatic brain injury; (2) to encourage scientists with established research programs in related areas to apply their efforts to brain injury research; and (3) to enable researchers with novel scientific and clinical ideas to test them and develop pilot data needed to develop a programmatic area of research that can be supported by additional funding from the National Institutes of Health, and other funding sources.

Programmatic Multi-Investigator Project Grant

The NJCBIR will fund Programmatic Multi-Investigator Project Grants that support collaborative research from at least 4 investigators from different laboratories with an emphasis on traumatic brain injury. Preference will be given to proposals that demonstrate complimentary approaches to addressing a research question through multidisciplinary investigations (e.g., molecular, genetic, physiologic and pharmacologic approaches).

Collaborations are encouraged among independent laboratories within the same institution, or among laboratories from different institutions. The principal investigator must be located within a qualifying institution in the State of New Jersey. Proposals must identify a principal

investigator within each research site as well as an overall Principal Investigator who is responsible for ensuring collaboration among all investigators. Applicants are encouraged to apply for a one-year or two-year award. Maximum funding is up to $1,000,000 per year including direct and indirect costs (10% maximum for the latter).

Maximum funding available for all grant categories in the 2006 grant cycle shall not exceed $4.2 million dollars.

For both the Individual Research Grants and Multi-Investigator Project Grants the Principal Investigators must be affiliated with a New Jersey State academic institution, research organization, public or private agency or other entity with demonstrated capability to conduct research responsibly. The principal investigator will hold an M.D., Ph.D. or equivalent advanced degree in a related scientific field. Unaffiliated individuals will not be funded. Individuals of any nationality or citizenship status may apply, provided they are employed by or affiliated with a qualified New Jersey State organization/institution.

Awards will begin on or about April 16, 2007. All qualifying institutions in the State of New Jersey may apply. Two-year awards are made through one-year contracts. Each funding award within the two-year period will be contingent upon the availability of funds. Second-year support for all grants is contingent upon submission and approval of a comprehensive progress report. All progress reports must be favorably reviewed by an independent scientific merit review panel and recommended to the NJCBIR for continued funding. A final progress report is required for all 1 and 2 year awards within 3 months after termination of the grant. All forms are available at www.nj.gov/health/njcbir.

Scientists supported by the NJCBIR are expected to report on their work at a symposium organized by the NJCBIR. Grantees will acknowledge the support of the New Jersey Commission on Brain Injury Research in all presentations and publications.

REVIEW PROCESS

All research proposals will be reviewed in accordance with the Grant Review Process set forth herein.

All grant applications must be submitted following the guidelines below. Grant applications that do not adhere to these guidelines will be returned to the applicant without further consideration. Grant applications sent by fax or e-mail will NOT be accepted.

The deadline for all grant applications to be received at the NJCBIR office is 5:00PM on October 2, 2006. No exceptions will be made.

All necessary and required grant application forms, progress reports, narrative reports, final narrative reports, policies, research guidelines, and other additional information can be viewed and downloaded from the NJCBIR website at www.nj.gov/health/njcbir.

Documents can also be obtained by sending a written request to the NJCBIR office at:

New Jersey Commission on Brain Injury Research
P.O. Box 360
Market and Warren Streets
Trenton, New Jersey 08625

LETTER OF INTENT

A one-page letter of intent is highly recommended for all grant applications. **Letters of intent must be filed with the NJCBIR office by September 2, 2006**.

PROPOSAL SUBMISSION

For all grant categories, one original (signed), and 25 additional copies of grant applications, plus 5 sets of reprints, appendices, and any attachments, must be sent to and received by the NJCBIR office no later than 5:00PM, October 2, 2006. Applicants must supply additional copies of appendices upon request. No grant applications will be accepted past this stated deadline.

Please use this address for all overnight mail deliveries (FedEx, UPS, USPS, Express Mail, etc.):

New Jersey Commission on Brain Injury Research
Health and Agriculture Building
Warren & Market Streets
5th Floor, Room 502
Trenton, New Jersey 08625

Please use this address for all regular U.S. mail deliveries:

New Jersey Commission on Brain Injury Research
P.O. Box 360
Health & Agriculture Building
Warren and Market Streets
Trenton, New Jersey 08625

GRANT REVIEW PROCESS

For all grant categories, the determination of grant awards will be made through a three-step review process:

1. **Administrative Review** (NJCBIR office):
   Upon receipt, all grant applications will be reviewed by the NJCBIR office for compliance with all applicable New Jersey State statutes and regulations, and to ensure completeness, and accuracy. In the event a grant application needs correction due to a budgetary issue, the applicant will be contacted to provide a revised budget.

2. **Independent Relevance Review** (Independent Relevance Review Panel):
   Independent relevance review will be conducted by a three-person panel appointed by the office of the NJCBIR. The Independent Relevance Review Panel will determine the relevance of all applications to the NJCBIR mission, priorities and Research Guidelines and will assign scientific reviewers for each proposal that meets those relevancy requirements. In the event the Independent Relevance Review Panel determines that an application does not meet those relevancy requirements, the application will be denied, and will not be forwarded for independent scientific merit review.

The decision to forward an application for independent scientific merit review is based only on relevance to the NJCBIR mission, priorities, and research guidelines, and does not guarantee that an award will be made.

3. **Scientific Merit Review** (Independent Scientific Merit Review Panel):
   Members of the Independent Scientific Merit Review Panel will convene to evaluate all grant applications forwarded by the Independent Relevance Review Panel, applying the criteria described below. This panel will assign scores to each application and make funding recommendations to the NJCBIR.

   If it is determined that *ad hoc* expertise is needed, additional scientific referees may be used.

   The Independent Scientific Merit Review Panel will forward its recommendations to the NJCBIR for final review and action. The authority to authorize or not authorize grants is fully vested in the NJCBIR according to New Jersey statute N.J.S.A. 52:9E-1-10.

CRITERIA FOR INDEPENDENT SCIENTIFIC REVIEW

Grant applications will be judged on scientific and technical merit, relevance to the NJCBIR's mission and priorities, clinical relevance, and interdisciplinary collaborations.

The independent scientific reviewers will perform two levels of review:

1. Each panel member will peer review his/her assigned proposals for scientific and technical merit and significance, and determine an initial score for each proposal.

2. The panel will then convene for group discussion, final scoring, and ranking of all proposals; the panel will also recommend a cut-off point for funding.

The following topics will be addressed during the review process:

- Is the research proposal of significance to the field of brain injury research?
- Is the proposed research innovative, including novel concepts, approaches, and/or methods?
- Is the research proposal relevant to NJCBIR priorities?
- Is the research proposal original in theory and application?
- Does prior research and theory provide a rational basis for the proposed research?
- Is the proposed project adequate in terms of experimental design and analyses, anticipation of potential problems, and consideration of alternative approaches?
- Does the design have adequate methodological quality and power to increase the likelihood of producing statistically sound conclusions?
- Does the researcher have access to appropriate facilities, equipment, expertise, and research environment either in-house and/or with collaborators or consultants?
- Does the design include interdisciplinary collaborations, and if so, is the proposed combination of disciplines both novel and likely to generate meaningful results?

- Are the qualifications, productivity, and time commitments of principal investigator and key staff commensurate with the proposed project?
- If a human model is proposed, is the availability of subjects adequate and system of education and protection of subjects appropriate?
- Is there evidence of compliance with National Institutes of Health regulations for the protection of animal welfare?
- Is the budget reasonable and justified for the project proposed? Is there evidence of institutional commitment and/or cost sharing in the proposal?
- Are there other factors both pro and con that may affect the ability of the applicant to successfully complete the research goals?
- Will the project make an original and important contribution to the field of brain injury research and more specifically, to the mission of the NJCBIR?

RESULTS NOTIFICATION

All applicants including Principal Investigators and organizations/institutions will be formally notified of the outcome of his/her application at the conclusion of the selection process anticipated to be no later than March 19, 2007. At that time, formal notification will be made to the institutions of successful applicants and contracts will be initiated shortly thereafter ***by the NJCBIR.***

Blinded reviews will be provided to both funded and non-funded applicants; no further information shall be provided.

Non-funded applicants also will be notified. There is no appeal process. All non-funded applicants in any given grant cycle are eligible to revise their applications based on reviewer feedback and reapply, one time only, through the reapplication process. All reapplications will be reviewed as new competing proposals.

ANTICIPATED RESULTS

The goal of the NJCBIR is to assume a catalytic role in the worldwide movement to develop effective methods of brain cell regeneration as a means to cure brain injury.

Through the judicious use of funds raised through violations under Title 39 of the Revised Statute, or any other motor vehicle, or traffic violation in the State of New Jersey, the NJCBIR will encourage and support meritorious scientific research in the State of New Jersey in fulfillment of that goal. This will benefit the State of New Jersey in savings on medical and support costs, enhance the development of the State's public and private biomedical sector, establish leadership in the field of brain cell repair, and most importantly, help develop effective interventions and cures for the disabilities associated with brain injury.